UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

SHARON BLACK and
MAX BLACK

Plaintiffs,

v.

COVIDIEN, PLC, et al.,

Defendants.

Case # 17-CV-6085-FPG

DECISION AND ORDER

INTRODUCTION

Plaintiffs Sharon Black and Max Black ("Plaintiffs") bring this product liability suit against Medtronic Inc. ("Defendant"), the manufacturer of an allegedly defective medical device implanted in Mrs. Black during surgery. Plaintiffs initially filed this suit in the Chemung County Supreme Court, raising negligence, design defect, failure to warn, breach of express warranty, breach of implied warranty, and loss of consortium claims. On February 7, 2017, Defendant removed the action to federal court. On February 13, 2017, Defendant moved to dismiss the Complaint for failure to state a claim. ECF No. 2.[1] Plaintiffs agreed to dismiss their breach of express and implied warranty claims, but maintain the remaining claims. For the reasons stated below, Defendant's Motion to Dismiss is GRANTED.

BACKGROUND[2]

Plaintiff Sharon Black had a history of hernia problems. On October 1, 2009, she underwent hiatal hernia repair surgery in Elmira, New York, during which her physician implanted

[1] Defendants correctly note that Plaintiffs incorrectly denominated Covidien, PLC and Tyco Healthcare Group LP as Defendants instead of Medtronic.
[2] The following allegations are taken from Plaintiff's Complaint (ECF No. 2-2) unless otherwise noted.

a piece of Medtronic's Parietex Composite mesh to reinforce Plaintiff's diaphragm and repair the hernia. On October 4, 2013, Ms. Black underwent an upper GI endoscopy. On December 9, 2013, doctors removed Plaintiff's stomach because it was damaged.

Plaintiff alleges that scientific "literature provides that small pore surgical mesh products" such as Parietex "generally induce a greater inflammatory response in host[s] than large pore surgical mesh products." ECF No. 2-2 at 10. The risk "of an adverse reaction to any surgical mesh product increases with the increase in the host's inflammatory response." *Id.* Plaintiff further alleges that the collagen used in Parietex "can cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction." *Id.* at 11. According to Plaintiff, Defendant marketed Parietex as a safe medical device in spite of the risks associated with it.

DISCUSSION

I. Legal Standard

Federal Rule of Civil Procedure 12(b)(6) provides that a party may move to dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In reviewing a motion to dismiss, a court "must accept as true all of the factual allegations contained in the complaint," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 572 (2007), and "draw all reasonable inferences in Plaintiff's favor." *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011). To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. These factual allegations "must be enough to raise a right to relief above the speculative level," *id.* at 545, and "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

II. Negligence

Plaintiffs allege that Defendant was negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling Parietex. The elements required to establish negligence are: (1) the defendant owed a duty of care to the plaintiff; (2) the defendant breached that duty; (3) the defendant's breach was a proximate cause of the plaintiff's injuries; and (4) the plaintiff was damaged. *Breitkopf v. Gentile*, 41 F. Supp. 3d 220, 271 (E.D.N.Y. 2014) (citing *Van Nostrand v. Froehlich*, 44 A.D.3d 54 (2d Dep't 2007)).

Plaintiffs have not adequately plead that the Parietex mesh proximately caused Mrs. Black's injuries. An injury is "proximately caused by an act, or a failure to act, whenever it appears from the evidence in the case that the act or omission played a substantial part in bringing about or actually causing the injury, and that the injury was either a direct result or a reasonably probable consequence of the act or omission." *Jund v. Town of Hempstead*, 941 F.2d 1271, 1286 (2d Cir. 1991). The Complaint asserts that Parietex's small pores and collagen induce a greater inflammatory response in hosts than other surgical mesh products, but it does not explain how, or even more fundamentally, if Mrs. Black developed an inflammatory response to Parietex. Even assuming Mrs. Black's body developed an inflammatory response to Parietex, Plaintiffs do not explain how or if that could have necessitated the removal of Mrs. Black's stomach.

Plaintiffs' response to Defendant's Motion to Dismiss supplements their Complaint with additional facts: Mrs. Black's medical record clearly implicates Defendant's product as the substantial factor in the cause of her injury, and doctors informed her in December 2013 that Parietex caused extensive damage to her stomach. If doctors and medical records did indeed indicate that Parietex caused Mrs. Black's stomach damage, those facts support finding proximate causation. *See Parillo v. Stryker Corp.*, 15-CV-155, 2015 WL 12748006, at *3 (N.D.N.Y. 2015)

(finding that plaintiff's allegations of product defect were not mere speculation because they were supported by a professional medical opinion). Without these additional facts, however, Plaintiff's assertion that Parietex was a substantial factor in causing Mrs. Black's injury is mere speculation and does not meet the *Iqbal-Twombly* standard.

Defendants argue that a host of alternative causes for Mrs. Black's stomach removal exist, including "a recurrence or worsening of her hiatal hernia, complications associated with comorbidities that often accompany and cause hiatal hernia like gastroesophageal reflux disease (GERD), or the development of a new medical condition completely unrelated to surgical mesh." ECF No. 7 at 3. Plaintiffs are not required to definitively rule out all of these alternative explanations at the pleading stage. *See Williamson v. Stryker Corp.*, No. 12 Civ. 7083, 2013 WL 3833081, at *6 (S.D.N.Y. July 23, 2013) ("[A]ll other possible causes may be eliminated as Plaintiffs obtain discovery and consult with an expert."). However, without any facts indicating that the Parietex mesh actually played any role in Mrs. Black's injury, the Court cannot credit Plaintiffs' conclusory allegations.

Even though Plaintiffs shared additional facts about Mrs. Black's medical record and doctors' opinions in their supplemental briefs, the Court must still dismiss their Complaint. *See Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir. 1984) ("[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.") (citing *Jacobson v. Peat, Marwich, Mitchell & Co.*, 445 F. Supp. 518, 526 (S.D.N.Y. 1977)). The Court may only consider the pleadings when deciding a motion to dismiss, and Plaintiffs' Complaint plainly fails to state a negligence claim.

III. Design Defect

Plaintiffs' strict liability design defect claim fails for the same reasons as their negligence claim.[3] To prove a design defect claim, a plaintiff must show that (1) the design created a substantial likelihood of harm; (2) a feasible design alternative existed at the time of manufacture such that the manufacturer's choice of design was not reasonable; and (3) the defective design was a substantial factor in causing plaintiff's injury. *Almonte v. Averna Vision & Robotics, Inc.*, 128 F. Supp. 3d 729, 740 (W.D.N.Y. 2015). Plaintiffs' Complaint plausibly alleges that Parietex's small pores and collagen rendered it defective and that safer meshes with larger pores made out of different materials existed at the time of manufacture. As the Court previously mentioned when it discussed proximate cause, however, the Complaint does not plausibly allege that Parietex's design was a substantial factor in causing Mrs. Black's injury.

IV. Failure to Warn

To succeed on a failure to warn claim, a plaintiff must prove that "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 F. App'x 8, 10 (2d Cir. 2011) (summary order) (citing *Liriano v. Hobart Corp.*, 92 N .Y.2d 232, 237 (1998)).

In New York, the manufacturer satisfies its duty to warn of a product's risks "by providing information to the prescribing physician, not to the patient directly." *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009). The court should dismiss a failure to warn claim if "a plaintiff does not plead facts indicating how the provided warnings were inadequate." *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 575 (E.D.N.Y. 2012). Plaintiffs fail in this regard because

[3] New York courts consider strict products liability and negligence claims to be "functionally synonymous." *See Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 258 (1995).

they claim that Defendant "failed to adequately warn Plaintiff or Plaintiff's physician(s) . . . of the risks of Parietex" (ECF No. 2-2 at 19), but they do not provide factual support for their assertion. Plaintiffs do not identify what warnings Defendant gave to Mrs. Black's physicians, how they were inadequate, or what warnings should have been given. The alleged "facts" supporting Plaintiffs' failure to warn claim are merely legal conclusions, which the court need not accept as true. *See Reed*, 839 F. Supp. 2d at 576 (E.D.N.Y. 2012) ("[A]ssertions that warnings were not 'adequate' or 'sufficient' are nothing more than legal conclusions unsupported by factual content."); *Iqbal*, 556 U.S. at 679 ("While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations."). Moreover, Plaintiffs have not pled proximate causation.

V. Loss of Consortium

Finally, the Court must dismiss Mr. Black's claim against Defendant for loss of consortium, as it is a derivative claim that cannot exist "independent of [Ms. Black's] right to maintain an action for injuries sustained." *Jordan v. Lipsig, Sullivan, Mollen & Liapakis, P.C.*, 689 F. Supp. 192, 198 (S.D.N.Y. 1988) (quoting *Liff v. Schildkrout*, 49 N.Y.2d 622, 632 (1980)). Because Plaintiffs' other claims fail, the loss of consortium claim is also dismissed.

VI. Leave to Amend

Plaintiffs request leave to amend their Complaint pursuant to Fed. R. Civ. P. 15. Leave to amend should be "freely granted," *id.*, in the absence of reasons such as "undue delay, bad faith" or "futility of amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962). Defendant argues that granting Plaintiffs leave to amend their Complaint would be futile because "Plaintiffs lack facts and evidence sufficient to allow them to point to a defect in Medtronic's mesh that allegedly caused Ms. Black's particular injuries." ECF No. 2 at 6. Plaintiffs' opposition to Defendant's Motion to

Dismiss, however, reveals additional facts that support Plaintiffs' claim for relief, namely that Mrs. Black's doctors and medical records indicated that the Parietex mesh damaged her stomach. If evidence supports these facts, they could ultimately support Plaintiffs' claim to relief. The Court therefore grants Plaintiffs' request for leave to amend.

CONCLUSION

For the reasons stated, Defendant's Motion to Dismiss (ECF No. 2) is GRANTED, and Plaintiffs' Complaint (ECF No. 1) is DISMISSED. Plaintiffs have until February 12, 2018 to file an Amended Complaint and serve it upon Defendant. *See* Loc. R. Civ. P. 15(c). Defendant must timely respond to the Amended Complaint in accordance with Federal Rule of Civil Procedure 15(a)(3). If Plaintiffs do not file an Amended Complaint by February 12, 2018, this case will be dismissed.

IT IS SO ORDERED.

Dated: January 26, 2018
Rochester, New York

HON. FRANK P. GERACI, JR.
Chief Judge
United States District Court